111TH CONGRESS
1ST SESSION

S. 1778

To amend the Federal Food, Drug, and Cosmetic Act with respect to generic drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 14, 2009

Mrs. SHAHEEN (for herself and Mr. VITTER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to generic drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Access to Affordable Medicines Act''.

SEC. 2. LABELING CHANGES.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

''(10) If the proposed labeling of a drug that is the subject of an application under this subsection is different from the labeling of the listed drug at the time the Secretary evaluates the application under this subsection, the drug that is the subject of such application shall, notwithstanding any other provision of this Act, be eligible for approval and shall not be considered misbranded under section 502 if—

''(A) a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of the expiration of the patent or exclusivity period that otherwise prohibited the approval of the drug under this subsection;

''(B) the Secretary has not determined the applicable text of the labeling for the drug that is the subject the application under this subsection at the time of expiration of such patent or exclusivity period;

''(C) the labeling revision described under subparagraph (A) does not include a change to the 'Warnings' section of the labeling;

''(D) the Secretary does not deem that the continued presence in commerce of the labeling of the listed drug (as in effect before the revision described

under subparagraph (A)) adversely impacts the safe use of the drug;

''(E) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

''(F) such application otherwise meets the applicable requirements for approval under this subsection.''.

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